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SmithKline Beecham Corporation and

SmithKline Beecham Corp. d/b/a GlaxoSmithKline

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

YVONNE JORDAN AND RANDALL
JORDAN,

Plaintiffs,

v.

MERCK & CO., INC., ROCHE
LABORATORIES INC., SMITHKLINE
BEECHAM CORPORATION,
GLAXOSMITHKLINE AND SMITHKLINE
BEECHAM CORPORATION D/B/A
GLAXOSMITHKLINE,

Defendants.

Case No: 1:08-cv-5554-JFK

**ANSWER TO COMPLAINT,
AFFIRMATIVE DEFENSES AND JURY
DEMAND**

DOCUMENT FILED ELECTRONICALLY

Defendants, Roche Laboratories Inc., SmithKline Beecham Corporation and SmithKline Beecham Corp. d/b/a GlaxoSmithKline (collectively "Roche and SmithKline"), by and through their undersigned counsel, Gibbons P.C., hereby Answer the Complaint. Roche and SmithKline deny all allegations set forth in the Complaint except to the extent such allegations specifically are admitted below. To the extent the allegations contained in any paragraph are directed to defendants other than Roche and SmithKline, Roche and SmithKline are not required to respond

to those allegations. To the extent a response is deemed necessary, Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of such allegations.

I.

JURISDICTION AND VENUE

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Roche and SmithKline deny the allegations. As for the remaining allegations contained in Paragraph 1 of the Complaint, Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of those allegations, except admit that Roche Laboratories Inc. is a Delaware corporation with a principal place of business in Nutley, New Jersey, that SmithKline Beecham Corporation is a Pennsylvania corporation with a principal place of business in Philadelphia, Pennsylvania, that there is no entity known as GlaxoSmithKline, and that SmithKline Beecham does business as GlaxoSmithKline.

**II.
PARTIES**

2. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint.

3. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 3 of the Complaint.

4. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of the Complaint.

5. Roche and SmithKline deny the allegations contained in paragraph 5 of the Complaint, except admit that Roche Laboratories Inc. is a Delaware corporation with a principal

place of business in Nutley, New Jersey.

6. Roche and SmithKline deny the allegations contained in paragraph 6 of the Complaint, except admit that SmithKline Beecham Corporation is a Pennsylvania corporation with a principal place of business in Philadelphia, Pennsylvania.

7. Roche and SmithKline deny the allegations contained in Paragraph 7 of the Complaint, except admit that Roche is permitted to do business in Utah and SmithKline is permitted to do business in the states of Utah and New York, and Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 7 of the Complaint.

8. Roche and SmithKline deny knowledge as to what is meant by the phrase “regularly transacted,” so the allegations in Paragraph 8 of the Complaint are denied. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 8 of the Complaint.

9. Roche and SmithKline deny the allegations contained in Paragraph 9 of the Complaint, except admit that Roche marketed, distributed and promoted Boniva® for prescription in accordance with its approved prescribing information and that SmithKline promoted Boniva® for prescription in accordance with its approved prescribing information. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 9 of the Complaint.

10. Roche and SmithKline deny the allegations contained in Paragraph 10 of the Complaint, except Roche and SmithKline admit only that it distributed Boniva® for prescription

in accordance with its approved prescribing information and deny any allegations in Paragraph 10 of the Complaint inconsistent with that prescribing information. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 10 of the Complaint.

11. Roche and SmithKline deny knowledge as to what is meant by the phrase “substantial revenue,” so the allegations in Paragraph 11 are denied. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 11 of the Complaint.

12. Roche and SmithKline deny knowledge as to what is meant by “consequences,” so the allegations in Paragraph 12 of the Complaint are denied. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 12 of the Complaint.

III. SUMMARY OF THE CASE

13. Roche and SmithKline deny the allegations contained in Paragraph 13 of the Complaint, except admit that Roche marketed, distributed and promoted Boniva® for prescription in accordance with its approved prescribing information and that SmithKline promoted Boniva® for prescription in accordance with its approved prescribing information. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 13 of the Complaint.

14. Roche and SmithKline deny the allegations contained in Paragraph 14, except are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 14.

15. Roche and SmithKline deny the allegations contained in Paragraph 15, except are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 15.

16. Roche and SmithKline deny the allegations contained in Paragraph 16, except are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 16.

17. Roche and SmithKline deny the allegations contained in Paragraph 17, except are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 17.

IV.

FACTUAL BACKGROUND

18. Roche and SmithKline deny the allegations contained in Paragraph 18 of the Complaint, except admit that Roche marketed, distributed and promoted Boniva® for prescription in accordance with its approved prescribing information and that SmithKline promoted Boniva® for prescription in accordance with its approved prescribing information. Roche and SmithKline are without knowledge or information sufficient to form a belief as to the truth of the allegations directed to defendants other than Roche and SmithKline in Paragraph 18 of the Complaint.

19. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 19 of the Complaint.

20. Roche and SmithKline deny the allegations contained in Paragraph 20, except that Roche and SmithKline admit that on May 16, 2003, Roche received approval from the Food & Drug Administration (“FDA”) to market Boniva® (ibandronate sodium) tablets “for the

treatment and prevention of postmenopausal osteoporosis and that on March 24, 2005, Roche received approval from the FDA to market Boniva® (ibandronate sodium) 150 mg Tablets “for once-monthly treatment of postmenopausal osteoporosis.” The specific text of approval letters from the FDA are incorporated herein by reference.

21. Roche and SmithKline admit only that Boniva® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 21 inconsistent with that prescribing information. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 21 of the Complaint.

22. Roche and SmithKline deny the allegations contained in paragraph 22 of the Complaint, except admit that Boniva® is a bisphosphonate and approved by the FDA for prescription in accordance with its approved prescribing information. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 22 of the Complaint.

23. Roche and SmithKline deny the allegations contained in Paragraph 23 of the Complaint.

24. Roche and SmithKline deny the allegations contained in Paragraph 24 of the Complaint.

25. Roche and SmithKline deny the allegations contained in Paragraph 25 of the Complaint.

26. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of the Complaint.

27. Roche and SmithKline deny the allegations contained in Paragraph 27 of the

Complaint.

28. Roche and SmithKline deny the allegations contained in Paragraph 28 of the Complaint.

29. Roche and SmithKline deny the allegations contained in Paragraph 29 of the Complaint.

30. Roche and SmithKline deny the allegations contained in Paragraph 30 of the Complaint.

31. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 of the Complaint.

32. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 of the Complaint.

33. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint.

34. Roche and SmithKline deny the allegations contained in Paragraph 34 of the Complaint.

35. Roche and SmithKline deny the allegations contained in Paragraph 35 of the Complaint.

36. Roche and SmithKline deny the allegations contained in Paragraph 36 of the Complaint.

37. Roche and SmithKline deny the allegations contained in Paragraph 37 of the Complaint.

38. Roche and SmithKline deny the remaining allegations in Paragraph 38 of the Complaint.

39. Roche and SmithKline deny the allegations contained in Paragraph 39 of the Complaint.

40. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 40 of the Complaint.

41. Roche and SmithKline deny knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 41 of the Complaint.

42. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 42 of the Complaint.

43. Roche and SmithKline deny the allegations contained in Paragraph 43 of the Complaint.

44. Roche and SmithKline deny the allegations contained in Paragraph 44 of the Complaint.

45. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 45 of the Complaint.

46. Roche and SmithKline deny the allegations contained in Paragraph 46 of the Complaint.

47. Roche and SmithKline deny the allegations contained in Paragraph 47 of the Complaint.

48. Roche and SmithKline deny the allegations contained in Paragraph 48 of the Complaint.

V. COUNTS

COUNT I. NEGLIGENCE

49. Roche and SmithKline repeat and reallege their responses contained in paragraphs

1 through 48 as though fully set forth at length herein.

50. The allegations in Paragraph 50 of the Complaint are conclusions of law to which no response is required. To the extent that a response is deemed necessary, the allegations are denied and Roche and SmithKline respectfully refer the Court to the relevant legal standard.

51. Roche and SmithKline deny the allegations contained in Paragraph 51 of the Complaint, including each and every allegation contained in subparts (a) through (f).

52. Roche and SmithKline deny the allegations contained in Paragraph 52 of the Complaint.

COUNT II. STRICT LIABILITY

53. Roche and SmithKline repeat and reallege their responses contained in paragraphs 1 through 52 as though fully set forth at length herein.

54. Roche and SmithKline deny the allegations contained in Paragraph 54 of the Complaint.

55. Roche and SmithKline deny the allegations contained in Paragraph 55 of the Complaint.

56. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 56 of the Complaint.

57. Roche and SmithKline deny the allegations contained in Paragraph 57 of the Complaint.

58. Roche and SmithKline deny the allegations contained in Paragraph 58 of the Complaint.

59. Roche and SmithKline deny the allegations contained in Paragraph 59 of the Complaint.

60. Roche and SmithKline deny the allegations contained in Paragraph 60 of the

Complaint.

61. Roche and SmithKline deny the allegations contained in Paragraph 61 of the Complaint.

62. Roche and SmithKline deny the allegations contained in Paragraph 62 of the Complaint.

63. Roche and SmithKline deny the allegations contained in Paragraph 63 of the Complaint.

COUNT III. BREACH OF EXPRESS WARRANTY

64. Roche and SmithKline repeat and reallege their responses contained in paragraphs 1 through 63 as though fully set forth at length herein.

65. Roche and SmithKline deny the allegations contained in Paragraph 65 of the Complaint, except Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations regarding defendants other than Roche and SmithKline and Boniva® in Paragraph 65 of the Complaint.

66. Roche and SmithKline deny the allegations contained in Paragraph 66 of the Complaint.

67. Roche and SmithKline deny the allegations contained in Paragraph 67 of the Complaint.

68. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 68 of the Complaint.

69. Roche and SmithKline deny the allegations contained in Paragraph 69 of the Complaint.

COUNT IV. BREACH OF IMPLIED WARRANTY

70. Roche and SmithKline repeat and reallege their responses contained in paragraphs

1 through 69 as though fully set forth at length herein.

71. Roche and SmithKline deny the allegations contained in Paragraph 71 of the Complaint, except admit that Roche marketed, distributed and promoted Boniva® for prescription in accordance with its approved prescribing information and that SmithKline promoted Boniva® for prescription in accordance with its approved prescribing information.

72. Roche and SmithKline deny the allegations contained in Paragraph 72 of the Complaint, except Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations regarding defendants other than Roche and SmithKline and Boniva®.

73. Roche and SmithKline deny the allegations contained in Paragraph 73 of the Complaint.

74. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 74 of the Complaint.

75. Roche and SmithKline deny the allegations contained in Paragraph 75 of the Complaint.

76. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 76 of the Complaint.

77. Roche and SmithKline deny knowledge or information sufficient to form a belief as to the truth of the contained in Paragraph 77 of the Complaint.

78. Roche and SmithKline deny the allegations contained in Paragraph 78 of the Complaint.

COUNT V. FRAUDULENT MISREPRESENTATION

79. Roche and SmithKline repeat and reallege their responses contained in paragraphs 1 through 78 as though fully set forth at length herein.

80. Roche and SmithKline deny the allegations contained in Paragraph 80 of the Complaint, including each and every allegation contained in subparts (a) and (b).

81. Roche and SmithKline deny the allegations contained in Paragraph 81 of the Complaint.

82. Roche and SmithKline deny the allegations contained in Paragraph 82 of the Complaint.

83. Roche and SmithKline deny the allegations contained in Paragraph 83 of the Complaint.

84. Roche and SmithKline deny the allegations contained in Paragraph 84 of the Complaint.

85. Roche and SmithKline deny the allegations contained in Paragraph 85 of the Complaint.

86. Roche and SmithKline deny the allegations contained in Paragraph 86 of the Complaint.

COUNT VI. FRAUDULENT CONCEALMENT

87. Roche and SmithKline repeat and reallege their responses contained in paragraphs 1 through 86 as though fully set forth at length herein.

88. Roche and SmithKline deny the allegations contained in Paragraph 88 of the Complaint, including each and every allegation contained in subparts (a) and (b).

89. Roche and SmithKline deny the allegations contained in Paragraph 89 of the Complaint.

90. Roche and SmithKline deny the allegations contained in Paragraph 90 of the Complaint.

91. Roche and SmithKline deny the allegations contained in Paragraph 91 of the

Complaint.

92. Roche and SmithKline deny the allegations contained in Paragraph 92 of the Complaint.

93. Roche and SmithKline deny the allegations contained in Paragraph 93 of the Complaint.

WHEREFORE, Defendants Roche Laboratories Inc., SmithKline Beecham Corporation and SmithKline Beecham Corp. d/b/a GlaxoSmithKline respectfully demand judgment dismissing Plaintiffs' Complaint with prejudice and awarding Roche and SmithKline its reasonable costs and disbursements, including reasonable attorneys' fees, together with such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations, doctrine of prescription, and/or is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of laches, estoppel and waiver.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because his alleged injuries were caused, solely, partially, or proximately by the intervening actions, omissions, representations, misrepresentations,

negligence, or breach of duty, of other persons, firms, or corporations that Roche and SmithKline do not control and for whom Roche and SmithKline are not legally liable and whose conduct they could not foresee or anticipate.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs' claims purport to impose requirements or standards different from, in addition to, or otherwise not identical to requirements or standards imposed by federal law and/or applicable state law governing the subject product, then said claims are preempted in accordance with the Supremacy Clause of the U.S. Constitution and by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and/or applicable state law.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Roche and SmithKline to warn Plaintiffs directly of alleged dangers associated with the use of Boniva®, such claims are barred under the learned intermediary doctrine because Roche and SmithKline has discharged their duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon Roche and SmithKline is subject to reduction by the application of the doctrine of comparative fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk

of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation distributed by Roche and SmithKline or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Roche and SmithKline and over whom Roche and SmithKline had no control and for whom Roche and SmithKline may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Boniva®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which Roche and SmithKline are not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Boniva® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to

implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Boniva®. The manufacture, marketing, and labeling of Boniva® was and is controlled by federal law, and Roche and SmithKline were at all times in compliance and obedience with applicable federal law. If Plaintiff's causes of action against Roche and SmithKline are permitted and allowed, they would impede, impair, interfere with, frustrate and/or burden the effectiveness of federal law regulating the field of prescription drugs and would constitute an invalid burden on interstate commerce. Accordingly, Plaintiff's claims are preempted by the Supremacy and Commerce Clauses of the United States Constitution, Article VI, Clause 2 and Article I, Section 8 respectively, as set forth in *Buckman Co. V. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), including any claim based in whole or in part on:

- a. any allegation of negligence *per se* or that Defendants violated federal regulations, including regulations promulgated or enforced by the Food and Drug Administration;
- b. any allegation that Defendants committed "fraud" on, or otherwise misled, made misrepresentations to, concealed material from, or violated reporting requirements imposed by any agency of the federal government, including the Food and Drug Administration;
- c. any allegation that Defendants' product was not "safe and effective" or that the risks of the drug outweighed its benefits;
- d. any allegation that Defendants failed to give Plaintiff's healthcare providers adequate warnings concerning the risks associated with the subject procedures; and/or

e. any allegation that, if accepted, would impose standards of care in addition to, or different from, those imposed by federal law, including federal regulations promulgated by the Food and Drug Administration.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for punitive damages are in contravention of Roche's and SmithKline's rights under each of the following constitutional provisions:

- a. the Commerce Clause of Article I, Section 8 of the United States Constitution;
- b. the Contracts Clause of Article I, Section 10 of the United States Constitution;
- c. the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution;
- d. the Supremacy Clause of Article VI of the United States Constitution;
- e. the Free Speech Clause of the First Amendment of the United States Constitution;
- f. the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;
- g. the Takings Clause of the Fifth Amendment of the United States Constitution;

h. the Right to Counsel of the Sixth Amendment of the United States Constitution;

i the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;

j. the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;

k. the Equal Protection Clause of the Fourteenth Amendment.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Roche and SmithKline, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages, such claim is barred because Boniva® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

As set forth in *BMW of North America v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003) and *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007), the Due Process Clause of the United States Constitution protects Roche and SmithKline from any award of damages that:

- a. is based, in whole or in part, on conduct which did not harm Plaintiff;
- b. is based, in whole or in part, on conduct and/or harm that occurred wholly outside New York;
- c. is based, in whole or in part, on conduct that is the exclusive province of federal law;

d. is based, in whole or in part, on comparisons of the relative wealth of Defendants and Plaintiff; or

e. is grossly disproportionate to the harm suffered by Plaintiff.

TWENTIETH AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive damages, Roche and SmithKline specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive damage awards which arose in the decision of *BMW of North America v. Gore*, 116 S. Ct. 1589 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 121 S. Ct. 1678, 1684-85 (2001), and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 123 S. Ct. 1513, 1519-26 (2003).

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Roche and SmithKline provided legally adequate "directions or warnings" as to the use of Boniva® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Boniva®.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Roche's and SmithKline's conduct conforms with medical knowledge.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-NINTH AFFIRMATIVE DEFENSE

All activities of Roche and SmithKline as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

THIRTIETH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Roche and SmithKline deny, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Roche and SmithKline's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Utah, and New York Constitutions.

THIRTY-SECOND AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Roche and SmithKline, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-THIRD AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Roche and SmithKline in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Roche and SmithKline were at all times done in good faith and without malice.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Roche and SmithKline knew or should have known and

which gave rise to a duty to warn, Roche and SmithKline at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

FORTIETH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

FORTY-FIRST AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-FIFTH AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

WHEREFORE, Defendants Roche Laboratories Inc., SmithKline Beecham Corporation and SmithKline Beecham Corp. d/b/a GlaxoSmithKline respectfully demand judgment dismissing Plaintiffs' Complaint with prejudice and awarding Roche and SmithKline its reasonable costs and disbursements, including reasonable attorneys' fees, together with such other and further relief that the Court may deem just and proper.

JURY DEMAND

Roche and SmithKline demand a trial by jury as to all issues so triable.

DATED: New York, New York
September 2, 2008

Respectfully submitted,

By: 

Michael R. Griffinger

GIBBONS P.C.

Attorneys for Defendants

Roche Laboratories Inc.,

SmithKline Beecham Corporation and

SmithKline Beecham Corp. d/b/a

GlaxoSmithKline

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CERTIFICATION OF SERVICE

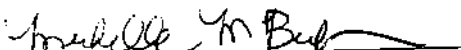
I hereby certify that on September 2, 2008, I caused a copy of the foregoing Answer To Complaint, Affirmative Defenses and Jury Demand of Roche Laboratories Inc., SmithKline Beecham Corporation and SmithKline Beecham Corp. d/b/a GlaxoSmithKline to be served via ECF on the following:

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I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.


Michelle M. Bufano

Dated: September 2, 2008